

Implementation of a Schedule II patient agreement for opioids and stimulants in an adult primary care practice

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ABSTRACT

Background: The consumption of controlled substances in North Carolina and the nation has created a health crisis with epidemic levels of medication diversion, abuse, overdose and death. Primary care providers are the principal prescribers of controlled substances and at greatest risk of encountering patients that abuse medications. Guidelines recommend patient agreements with monitoring requirements when prescribing opioids and stimulants. Studies have focused on opioids and excluded stimulants. Adherence to recommended monitoring requirements has not been fully evaluated. **Methodology:** This was a quality improvement project using the Plan-Do-Check-Act procedure. The following outcome measures were evaluated: signed agreement on file, prescription monitoring program (pmp) checks, urine screens, and prescriptions written without a mandatory visit. **Implementation:** Who: patients aged 19 and over prescribed a long-term Schedule II medication for the chronic conditions of pain and/or attention deficit hyperactivity disorder. What: implemented a patient agreement and measured fidelity to components of the agreement. When: seven months pre- to seven months post-implementation. Where: in an adult primary care practice with approximately 2,500 patients. How: an agreement was implemented with monthly feedback provided. **Results:** Post-implementation, 94% of patients meeting criteria had a signed agreement in their medical record. Adherence to urine screening improved from 5.3% to 71.1%. Guideline adherence to pmp checks improved from 11.3% to 99.0%. Guideline deviation for prescriptions written without a visit improved from 20.6% to 0%. All improvements were statistically significant ($P < .001$). **Conclusion:** A Schedule II controlled substance patient agreement was successfully implemented in a primary care practice reducing risk for both the patient and provider.

Keywords: Adherence monitoring, adult, controlled substances, patient agreement, prescription opioids, primary care

Introduction

The consumption of controlled substances has increased dramatically in North Carolina and across the nation. The result is a public health crisis with epidemic levels of medication diversion, misuse, abuse, unintentional overdose, and death.^[1-7] Schedule II medications are controlled substances that fall into two distinct categories: opioid analgesics used to treat pain and nonnarcotic stimulants popular for treating attention deficit hyperactivity disorder (ADHD). US consumption of Schedule II medications, most notably opioids, exceeds that of any other country in the world. Currently, Americans consume 99% of the global

hydrocodone supply and 78% of the global oxycodone supply but comprise only 4.6% of the world's population.^[8-10] The centers for disease control reports that in 2014, opioid-related deaths totaled 28,647 which is 61% of all drug overdose fatalities.^[11]

In response to this increase in unintentional deaths, the Centers for Disease Control and Prevention (CDC) published a 2016 guideline for prescribing opioids for chronic pain.^[12] The guideline includes 12 specific recommendations to guide providers in three areas: (1) when to initiate or continue opioids, (2) how to select, dose, continue or discontinue opioids, and (3) how to assess risk and harm of opioids. Also in 2016, the Interagency Pain Research Coordinating Committee

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published the “National Pain Strategy.”^[13] This report highlights strategies to address the continuing problem of unrelieved chronic pain and how to treat it in the context of increased unintentional deaths from opioids. The report highlights the need for improvements in the clinical delivery of pain therapies and the need for professional education and training in chronic pain. Both reports are critical to primary care providers because they are the principal prescribers of controlled substances and a major source of potentially harmful medications.^[4,10,12,14-18] As deaths from overdose increase, primary care providers become reluctant to prescribe controlled medications fearing litigation, regulatory issues, and loss of professional license. In response, the American Pain Society, the Federation of State Medical Boards, and the North Carolina Medical Board published detailed and comprehensive guidelines to encourage responsible prescribing with the goals of increasing patient safety and reducing prescriber risk.^[18-20] The recommendations included patient agreements and monitoring tools such as urine screens, early refill restrictions, and prescription monitoring programs.

Consensus regarding best practice is that patient agreements assist health-care providers in reducing risks associated with the prescription of controlled substances and promote patient safety by increasing patient commitment to the prescribed plan of care.^[2,3,10,21-26] The Federation of State Medical Boards developed a patient agreement model that incorporates many of the recommended monitoring tools and the agreement has been endorsed by the joint commission and adopted or adapted by 46 states.^[20,27]

Before May 1, 2015, the clinical setting reported in this manuscript did not offer a Schedule II controlled substance patient agreement. Urine screens and prescription monitoring checks were performed randomly at the discretion of the physician. The health-care team acknowledged that the potential diversion, misuse, and abuse of controlled substances coupled with the lack of a patient agreement and limited adherence monitoring, placed the patient, prescriber, practice, and public at risk.

A Schedule II controlled substance patient agreement was introduced in an effort to improve the care of patients prescribed long-term controlled substances and to control potential medication resale and abuse, a task the physicians viewed as their social responsibility. The patient agreement bundled three measures: urine screens, prescription monitoring program checks, and prescriptions written without a 3 month mandatory visit. Fidelity to the bundled elements was compared 7 months pre- and post-implementation of the patient agreement to determine the effect of the practice change.

Materials and Methods

Design

This quality improvement project used a pre/post design to compare data 7 months pre- to 7 months post-implementation

of a Schedule II controlled substance patient agreement in an adult primary care practice. The 7-month time frame allowed for at least two medication management visits scheduled at 3-month intervals. The project was reviewed by the Duke University Institutional Review Board and deemed exempt.

Setting

The clinical setting was an adult primary care practice located in a small, urban area in North Carolina with approximately 2500 patients, two physicians, two licensed nurses, and no advanced practice nurses or nurse practitioners. The practice accepted private insurance and Medicare but did not accept Medicaid.

Sample

All patients age 19 and over prescribed a long-term Schedule II medication for the chronic conditions of pain (ICD-10 G89.4) and/or ADHD (ICD10 F90.0) were initially included in the sample. The following exclusion criteria were used: pregnancy, discontinuation of medication, loss of insurance coverage, decision to have medications prescribed elsewhere (i.e., psychiatrist, pain specialist, etc.), and no-show during the study period. The final sample size was $n = 50$. Only patient visits directly related to the prescribing of Schedule II controlled substance medications were included in the dataset. Unrelated visits were excluded from this study.

Schedule II controlled substance patient agreement

Sample patient agreement models were retrieved online, reviewed and modified to fit the needs of the clinical setting. The final patient agreement included a clear purpose statement and prescription policy. Responsibilities of the patient and physician were clearly described. Privacy issues were addressed as well as the implications of a patient's refusal to sign or abide by the agreement. The agreement required the following practice changes: a signed, Schedule II patient agreement in the patient's medical file; check of the state-implemented prescription monitoring program at each clinic visit pertaining to controlled substances; random urine screens at least one screen/patient/12 months period; and no prescriptions written outside a 3-month mandatory visit.

Implementation

The patient agreement was developed and adopted by the practice before the implementation date of May 1, 2015. Throughout development and implementation of the agreement, the physicians remained sensitive to the drug seeker stereotype often endured by patients prescribed controlled substances. The physicians created and presented the agreement as a proactive patient education and safety tool, not a punitive, law enforcement-type activity.^[15] Staff and providers received education throughout the project process. One week before implementation, a formal training session was held to answer remaining questions regarding the patient agreement and policy.

Data were collected and tracked weekly to measure policy adherence to protocol and to identify the necessary process or education changes to influence continual improvement. Data were shared with providers at monthly staff meetings.

The Schedule II controlled substance patient agreement was implemented in the practice setting beginning May 1, 2015. The nurse presented the agreement to the patient, explained its contents, and asked the patient to carefully review the contract before the physician entered the examination room. The physician addressed any contract questions or concerns presented by the patient. Then, the patient and physician signed the contract. After verifying signatures, the office assistant placed the contract in the patient's medical record. The clinical setting used both electronic and paper charts. The patient agreement was presented in paper format. The document was scanned into electronic charts and filed into paper charts. The patient was offered a copy as a personal record.

During patient visits, nurses collected and processed urine samples as ordered by the physician. Per protocol, one urine drug screen was required per 12 months period. Samples were sent to a contracted laboratory facility for analysis. Urine screen results were received from the laboratory in both paper and electronic format and entered into patient files accordingly. A nurse was assigned to check the statewide prescription monitoring program before all scheduled medication management visits. The prescription monitoring program report document was scanned into electronic charts and filed in paper charts.

Outcome variables

The primary outcomes were a patient agreement on file and adherence to three components bundled in the patient agreement. The variable "signed agreement on file" represented the number of patients with signed agreements in their chart postimplementation. Pre/post variables included, (1) urine screen—a measurement that compared the number of urine screens performed on matched pairs pre- and post-implementation to determine the percentage of adherence to agreement guidelines, (2) prescription monitoring program check—a measure of checks completed on the statewide prescription monitoring system and documented in the medical record divided by the number of patient visits to determine the percentage of adherence to agreement guidelines; and (3) prescriptions written without a mandatory visit—a measure of prescriptions written for patients that did not fulfill the mandatory 3-month controlled substance patient visit divided by the number of patient visits and potential visits (phone calls and/or portal messages) to determine the percentage of deviation from agreement guidelines. Demographic and descriptive data included gender, age, race, and diagnosis code.

Medical records audit

Paper and electronic files were accessed retrospectively to abstract preimplementation data from Jan 1, 2014, to July 31, 2014. Postimplementation data were collected through the

patient medical record within one week of all Schedule II related medication management visits.

Analysis

Descriptive statistics were used to describe sample characteristics. The percentage of patients with a signed agreement postimplementation was determined by dividing the number of patients with a signed agreement in their chart by the number of patients meeting the inclusion criteria. Because patient agreements were not used in the practice setting before the project, a pre-post comparison was not possible. Nonparametric tests were used to compare percentage averages pre- and post-implementation for the three remaining outcome variables. Adherence to urine screen testing was measured using McNemar's test to determine the difference between paired proportions of patients screened preimplementation versus patients screened postimplementation. Wilcoxon's signed rank test was used to calculate the significance of the pre/post percentage differences for prescription program monitoring and prescriptions written without a mandatory visit. The nonparametric tests were performed using IBM's Statistical Package for Social Sciences (SPSS) version 22 IBM (International Business Machines, Armonk, NY).

Results

The initial sample included 69 patients, 19 of which met valid exceptions for not signing a patient agreement, leaving a final sample of $n = 50$ patients. Exclusions included pregnancy ($n = 1$), no-show during study ($n = 5$), medication discontinued ($n = 6$), medication prescribed elsewhere ($n = 5$), and loss of insurance ($n = 2$). Table 1 displays a detailed description of the sample characteristics. The mean (standard deviation) age was 50.7 (16.3). Of the final sample ($n = 50$), the majority of patients were white (96.0%) and female (62.0%). There was almost an equal proportion of Schedule II medications prescribed for chronic pain and ADHD. Table 2 reports changes in adherence to

Table 1: Sample characteristics ($n=50$)

Variable	<i>n</i> (%)
Age	
<30	7 (14.0)
30-44	10 (20.0)
45-59	11 (22.0)
60+	22 (44.0)
Race	
White	48 (96.0)
Black	1 (2.0)
Latino	1 (2.0)
Gender	
Male	19 (38.0)
Female	31 (62.0)
Diagnosis	
Chronic pain	25 (50.0)
ADHD	23 (46.0)
Both	2 (4.0)

ADHD: Attention deficit hyperactivity disorder

Table 2: Comparison of pre-to post-implementation outcomes

Variable	Preimplementation (%)	Postimplementation (%)	P
Signed agreement in chart (signed agreements/ <i>n</i> =50)	0	47 (94.0)	NA
Urine screens (urine screens/ <i>n</i> =38)*	2 (5.3)	27 (71.1)	<0.001
Prescription Monitoring Program checks (checks completed per patient/number of visits per patient; then calculated overall percent adherence)**	11.3 ^a	99.0 ^a	<0.001
Prescriptions written without mandatory visit (prescriptions written/number of visits and potential visits [phone calls and portal messages] per patient; then calculated overall percent deviation)**	20.6 ^b	0 ^b	<0.001

*McNemar test for matched pairs (38 patients with matched, pre/post visits within study period); **Wilcoxon signed rank test for related samples; ^aPercent adherence to guideline; ^bPercent deviation from guideline

or deviation from the elements of the signed agreement between the pre- and post-implementation periods. All measurements improved significantly postimplementation: signed agreements in chart exceeded the 90% compliance goal and all pre/post measures were statistically significant ($P < 0.001$).

Discussion

Guidelines and regulations for the prescribing of controlled substances have been available for more than 5 years and have been proven to reduce risk and improve patient compliance.^[21-26] In spite of guideline success, the CDC and The National Pain Council reported as recently as March 2016 that providers do not consistently implement practices such as patient agreements, prescription monitoring programs, and urine screens that decrease the risk for misuse.^[12,13] Providers assert that guideline compliance interrupts the normal clinical workflow and consumes valuable time.^[12] We conducted this quality improvement project to demonstrate that it is possible to successfully implement in a small primary care practice a patient agreement and monitoring policy that fulfills governmental guidelines and recommendations for prescribing Schedule II medications for chronic conditions such as pain and ADHD.

Implementation of the recommended opioid prescribing practices can be daunting, and noncompliance with recommendations has been addressed in numerous studies. Hariharan *et al.* retrospectively examined patient agreement adherence and cancellation.^[22] The authors determined that primary care physicians did not routinely monitor for patient agreement adherence, did not have standardized protocol for urine screening, and performed urine screens on <45% of eligible patients. Khalid *et al.* analyzed physician adherence to opioid prescribing guidelines and potential patient opioid misuse based on physician status of either attending or resident.^[18] Less than half of patients in either group were presented with a patient agreement, less than two-thirds received a urine screen, and over one-third were granted multiple, early refills. Lasser *et al.* reported baseline characteristics for three primary care study sites. On average, 45.3% of patients were offered a patient agreement, 39.7% received urine screens, and 35% received early refills.^[16] After implementation of four strategies (nurse care management, use of a patient registry, academic detailing, and electronic tools), the authors determined that provider adherence to prescribing guidelines improved. Similar to our project, these studies concluded that intervention

components related to safe prescribing guidelines for controlled substances have the potential to increase provider adherence and reduce patient misuse of controlled medications. Unlike our study, the authors focused specifically on opioid-related measures and excluded stimulants, an important, but often overlooked, category of Schedule II medications.

In our study, a large proportion of patients received prescription stimulants. Federal and state agencies have grouped opioids and stimulants under the same Schedule II umbrella and impose identical guidelines and regulations, but the potential illegal uses and outcomes of opioids versus stimulants are quite different. Opioids have a greater potential for addiction, overdose, and death. Stimulants, or nonnarcotics, have a greater potential for diversion and misuse. Stimulant abuse is often ignored in the Schedule II literature, but diversion and misuse is a growing problem, especially in the college-age population.^[28] Our study adds to the literature in that it examined not only the number of signed patient agreements but also measured adherence to specific components of the agreement and monitored both narcotics and stimulants in a time and cost-effective manner.

To the best of our knowledge, this is the first study to measure improvements in adherence to the bundled components of a signed, Schedule II patient agreement after implementation in a primary care practice. Implementation was a success in that it enhanced the prescribers' ability to continue to safely meet the medication needs of their patients while reducing prescriber risk. All reported measures dramatically improved from pre- to post-time periods. Adherence to guidelines for both urine screen monitoring and prescription monitoring program checks increased significantly. The physicians' commitment to not writing prescriptions outside the 3-month mandatory visit was especially impressive with no prescriptions written postimplementation outside the 3-month window.

The implementation process was compatible with the office workflow. While we did not directly measure cost, we believe the associated implementation cost was minimal. The time cost factor to introduce and explain the agreement to patients was negligible. The nurse staff performed all prescription monitoring checks during slow periods of the day. The monitoring program was state funded with free access to registered users. The patient

incurred drug screening costs only in circumstances where insurance refused payment. In these rare cases, the tests were billed at the physician's fee, which is a substantially discounted rate. No patient complaints with regard to laboratory costs were received.

Some barriers to implementation were encountered. During the implementation, the laboratory that performed the urine screens introduced new software that required staff training and complicated the creation of custom laboratory panels necessary for drug-specific testing. Three patients expressed privacy concerns regarding urine screens. The concerns did not arise while signing the agreement but at the time of urine collection. Patients were reminded that the tests were specific only to the medication prescribed and included no other results or information. No patients refused to provide a urine sample for screening or refused to sign the agreement. Three patients have no agreement on file because the nurse forgot to offer the opportunity to review and sign the contract.

Limitations

Several limitations apply to our project. The project was conducted in a single, private practice with only two providers and a specific, local culture. Both providers were extremely motivated and engaged in the project. Results are not generalizable to larger practices with multiple providers in which implementation may be more challenging. Our experience can be translated to the many small, primary care practices seeking to comply with the current guidelines for prescribing Schedule II controlled substances. Patients prescribed Schedule II medications were overwhelmingly Caucasian (96%) and aged <60 (44%) and may not be applicable to patients with differing demographic characteristics. Adherence was not monitored beyond 7 months postimplementation. Individual practices should actively monitor policy adherence until the practice pattern becomes embedded in daily routine. No data were collected with regard to the patient's or physician's perception of the policy. While we did not collect this data, patients repeatedly expressed a clear understanding of the purpose of the agreement and seemed to view the contract positively. The providers showed support of the agreement by striving to adhere to agreement components. We did not collect preexisting substance abuse or other risk factors of opioid addiction or misuse. This data would be helpful in describing whether or not the population studied was high risk for opioid abuse. Finally, no data were collected regarding patient outcomes, therefore, we do not know if pain continued to be adequately managed. Despite these limitations, the project demonstrated the ability to introduce a Schedule II controlled substance patient agreement in a small primary care practice with excellent adherence to the required components of the contract. Future studies should replicate this project at several practices with different practice characteristics and monitor adherence for a longer duration.

Conclusion

The implementation of a Schedule II controlled substance patient agreement and prescribing policy in a small primary care practice was feasible and significantly improved the number of patient agreements signed, annual urine screens performed, and prescription monitoring program checks completed; and significantly decreased the number of Schedule II prescriptions written outside a mandatory 3-month office visit.

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Conflicts of interest

There are no conflicts of interest.

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